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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: 38349-0102D

Applicant: Gholam-Reza Zadno-Azizi, *et al.*
Serial No.: 10/081,569
Filed: February 21, 2002
For: BODY FLUID FLOW CONTROL
DEVICE
Art Unit: 3738
Examiner: Urmi Chattopadhyay

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**REQUEST FOR INTERFERENCE
UNDER 37 C.F.R. §1.607(a)**

Commissioner for Patents
Washington, DC 20231

Dear Sir:

Pursuant to 37 C.F.R. §1.607, Applicants hereby request that an interference be declared between the above-captioned patent application and U.S. Patent No. 6,293,951 to Alferness ('951 patent). A copy of the '951 patent is attached hereto. Claims 16-25 are pending in the instant application. Applicants added claims 16-19 to the instant application in a preliminary amendment dated August 16, 2002. Applicants added claims 20-25 to the instant application in a preliminary amendment dated November 7, 2002.

Presentation of Counts

Pursuant to 37 C.F.R. §1.607(a)(2), Applicants present the following proposed counts:

Count 1:

A pulmonic fluid-flow control device, comprising:

a one-way valve dimensioned for pulmonary placement, wherein the valve is configured to restrict fluid flow.

Count 2:

A pulmonic fluid-flow control system, comprising:

an elongate passage or outer sheath for positioning a valve; and

a one-way valve so dimensioned as to be guidable on the elongate passage or into the outer sheath, the valve so dimensioned for pulmonary placement, wherein the valve is configured to restrict fluid flow.

Identification of '951 Patent Claims Corresponding to the Proposed Counts

Pursuant to 37 C.F.R. §1.607(a)(3), Applicants hereby identify the claims of the '951 Patent that correspond to the proposed counts:

'951 Patent Claims Corresponding to Count 1

Claims 1 and 22 of the '951 patent correspond to Count 1. The correspondence between claims 1 and 22 of the '951 patent and Count 1 is explained in detail below.

Claims 2-8 of the '951 patent depend from claim 1 and, therefore, also correspond to Count 1.

'951 Patent Claims Corresponding to Count 2

Claims 9 and 23 of the '951 Patent correspond to Count 2. The correspondence between claims 9 and 23 of the '951 patent and Count 2 is explained in detail below.

Claims 10-16 of the '951 patent depend from claim 9 and, therefore, also correspond to Count 2.

Identification of Pending Claims Corresponding to the Proposed Counts

Pursuant to 37 C.F.R. §1.607(a)(4), Applicants hereby identify the pending claims of the instant application that correspond to the proposed counts:

Pending Claims Corresponding to Count 1

Pending claims 16, 18, 20, 21 and 22 correspond to Count 1.

Claim 16 of the instant application and claim 1 of the '951 patent correspond to Count 1 in that these claim both relate to a "bronchial sub-branch obstruction device", which corresponds to the "pulmonic fluid-flow control device" of Count 1. Both claims include "an obstructing member dimensioned for insertion into a bronchial sub-branch communicating with a portion of the lung to be reduced in size, the obstructing member having an outer dimension which is so dimensioned as to make continuous contact with an inner dimension of the bronchial sub-branch." This corresponds to the "one-way valve dimensioned for pulmonary placement," as recited in Count 1. Both claims further recite that the "the obstructing member is a one-way valve to permit exhaled air to flow from the lung portion while precluding inhaled air from flowing into the lung portion," which corresponds to the portion of Count

1 that recites that the one-way valve “is configured to restrict fluid flow.” The claims both contain additional functional language that is not recited in Count 1.

Claim 18 of the instant application and claim 22 of the '951 patent correspond to Count 1 in that these claims both relate to a “bronchial sub-branch obstruction device”, which corresponds to the “pulmonic fluid-flow control device” of Count 1. Both claims recite “an obstructing member dimensioned for insertion into a bronchial sub-branch communicating with a portion of the lung to be reduced in size, the obstructing member having an outer dimension which is so dimensioned as to make continuous contact with an inner dimension of the bronchial sub-branch.” This corresponds to the “one-way valve dimensioned for pulmonary placement,” as recited in Count 1. Both claims further recite that the “the obstructing member is a one-way valve to permit exhaled air to flow from the lung portion while precluding inhaled air from flowing into the lung portion,” which corresponds to the portion of Count 1 that recites that the one-way valve “is configured to restrict fluid flow.” Both claims contains additional functional language that is not recited in Count 1.

Claim 20 of the instant application corresponds exactly to Count 1. Claims 21 and 22 both depend from claim 20 and, therefore, also correspond to Count 1.

Pending Claims Corresponding to Count 2

Pending claims 17, 19, 23, 24, and 25 correspond to Count 2.

Claim 17 of the instant application and claim 9 of the '951 patent correspond to Count 2 in that these claims both relate to a “bronchial sub-branch obstruction system,” which corresponds to the “pulmonic fluid-flow control system” of Count 2. The claims both include “a conduit configured to be passed down a trachea, into a bronchus communicating with the trachea, and into a bronchial sub-branch communicating the bronchus with a lung portion to be reduced in size.” This corresponds to the “elongate passage or outer sheath for positioning a valve” that is recited in Count 2. Both claims further recite “an obstructing member so dimensioned as to be guidable through the conduit and placed in the bronchial sub-branch.” This corresponds to the portion of Count 2 that recites “a one-way valve so dimensioned as to be guidable on the elongate passage or into the outer sheath, the valve so dimensioned for pulmonary placement.” Both claims also recite that the “the obstructing member is a one-way valve to permit exhaled air to flow from the lung portion while precluding inhaled air from flowing into the lung portion.” This corresponds to Count 2, which recites that the “the valve is configured to restrict fluid flow.” The claims both contain additional functional language that is not recited in Count 1.

Claim 19 of the instant application and claim 23 of the '951 patent correspond to Count 2 in that these claims both relate to a “bronchial sub-branch obstruction system,” which corresponds to the “pulmonic fluid flow control system” of Count 2. Both claims include “a conduit configured to be

passed down a trachea, into a bronchus communicating with the trachea, and into a bronchial sub-branch communicating the bronchus with a lung portion to be reduced in size.” This corresponds to the “elongate passage or outer sheath for positioning a valve”, as recited in Count 2. Both claims further recite “an obstructing member so dimensioned as to be guidable through the conduit and placed in the bronchial sub-branch.” This corresponds to Count 2, which recites “a one-way valve so dimensioned as to be guidable on the elongate passage or into the outer sheath, the valve so dimensioned for pulmonary placement.” Both claims also recite that the “the obstructing member is a one-way valve to permit exhaled air to flow from the lung portion while precluding inhaled air from flowing into the lung portion.” This corresponds to the portion of Count 2 that recites “the valve is configured to restrict fluid flow.” Both claims contain additional functional language that is not recited in Count 1.

Claim 23 of the instant application corresponds exactly to Count 2. Claims 24 and 25 both depend from claim 23 and, therefore, also correspond to Count 2.

Compliance with 35 U.S.C. § 135(b)

As discussed above, claims 16, 17, 18, and 19 of the instant application are based on claims 1, 9, 22 and 23, respectively, of the '951 patent. Thus, claims 16, 17, 18, and 19 claim the same subject matter as claims 1, 9, 22, and 23 of the '951 patent. Claims 16, 17, 18, and 19 were added to the instant application in a preliminary amendment mailed to the U.S. Patent Office via Express Mail on August 16, 2002. The '951 patent

issued on September 25, 2001. Thus, claims 16, 17, 18, and 19 were pending in the instant application prior to one year from the date on which the '951 patent was granted. Accordingly, the requirements of 35 U.S.C. § 135(b) are satisfied.

Application of Terms of Claims to the Disclosure of the Application

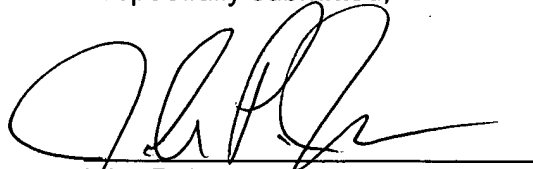
Pursuant to 37 C.F.R. §1.607(a)(5), claims 16-25 of the instant application find support in the disclosure of the application as filed, as indicated in the attached table entitled, "APPLICATION OF CLAIM TERMS TO APPLICATION".

Showing Under 37 C.F.R. §1.608(a)

The instant application is a continuation of U.S. Patent Application Serial No. 09/397,218, filed September 16, 1999, which is a continuation of U.S. Patent Application Serial No. 08/931,552, filed September 16, 1997, issued as U.S. Patent No. 5,954,766. Thus, the effective filing date of the instant application is September 16, 1997. The filing date of the '951 patent is August 24, 1999, which is almost two years after the effective filing date of the instant application. Accordingly, pursuant to 37 C.F.R. §1.608(a), there is a basis upon which the applicants are entitled to a judgment relative to the patentee of the '951 patent.

The claims of the present application are supported by the specification as filed, and are entitled to a priority date of at least September 16, 1997. The '951 patent was filed on August 24, 1999. Therefore, Applicants are entitled to senior party status.

Respectfully submitted,



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APPLICATION OF CLAIM TERMS TO APPLICATION

APPLICATION OF TERMS OF CLAIM 16 TO APPLICATION

Claim 16 of the '569 application	Exemplary Disclosure of '569 application
A bronchial sub-branch obstruction device for reducing the size of a lung comprising	<p>p.3, lines 4-6 "...a flow control device for the human body such as for ...pulmonic placement."</p> <p>p.2, lines 13-16 "a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of ... a one-way flow restriction."</p>
an obstructing member dimensioned for insertion into a bronchial sub-branch communicating with a portion of the lung to be reduced in size,	<p>p.6, lines 6-8 "In the expanded state, the overall device is intended to fit with interference with the duct or passageway. Before expansion, easy insertion is contemplated with clearance."</p> <p>p.7, lines 7-9 "The frame is cylindrical with an OD in the insertion state of approximately .329[inches], a length of approximately .304[inches] and a thickness of approximately .005[inches] to .015[inches]."</p>
the obstructing member having an outer dimension which is so dimensioned as to make continuous contact with an inner dimension of the bronchial sub-branch to seal the bronchial sub-branch upon placement in the bronchial sub-branch, to preclude normal function of the lung portion, and to collapse the portion of the lung for reducing the size of the lung,	<p>p.6, lines 6-7 "In the expanded state, the overall device is intended to fit with interference with the duct or passageway."</p> <p>p.7, lines 7-9 "The frame is cylindrical with an OD in the insertion state of approximately .329[inches], a length of approximately .304[inches] and a thickness of approximately .005[inches] to .015[inches]."</p> <p>p.4, lines 3-6 "The device includes a resilient seal 20 which, in this first embodiment, includes a cylindrical elastomeric or, more generally, polymeric material capable of sealing within the interior of a body duct or passageway."</p>

	<p>p. 4, lines 8-9 "[T]he seal has a substantially circular cross-section to fit within the body duct or passageway."</p> <p>p.7, lines 5-6 "...the outside diameter of the resilient seal 20 is approximately .349 [inches]"</p>
<p>wherein the obstructing member is a one-way valve to permit exhaled air to flow from the lung portion while precluding inhaled air from flowing into the lung portion.</p>	<p>p.4, lines 2-3 "Figures 1 and 2 illustrate a first fluid flow control device capable of one-way flow..."</p> <p>p. 5, line 5 "The valve body 24 acts in this embodiment as a one-way valve...."</p> <p>p.16, line 5 "One-way valve operation may be provided..."</p> <p>p.2, lines 13-16 "a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of ... a one-way flow restriction."</p>

APPLICATION OF TERMS OF CLAIM 17 TO APPLICATION

Claim 17 of the '569 application	Exemplary Disclosure of '569 application
<p>A bronchial sub-branch obstruction system for reducing the size of a lung comprising:</p>	<p>p.3, lines 4-6 "...a flow control device for the human body such as for ...pulmonic placement."</p> <p>p.2, lines 13-16 "a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of ... a one-way flow restriction."</p>
<p>a conduit configured to be passed down a trachea, into a bronchus communicating with the trachea, and into a bronchial sub-branch communicating the bronchus with a lung portion to be reduced in size; and</p>	<p>p.3, lines 4-6 "...a flow control device for the human body such as for ...pulmonic placement."</p> <p>p.11, lines 12-14 "Another mechanism for providing an elongate</p>

	expander and insertion tool is illustrated in Figure 12. The device includes an outer sheath 88 into which is positioned a fluid flow control device ..."
an obstructing member so dimensioned as to be guidable through the conduit and placed in the bronchial sub-branch to seal the bronchial sub-branch, to preclude normal function of the lung portion, and to collapse the lung portion,	<p>p.11, lines 12-14 "Another mechanism for providing an elongate expander and insertion tool is illustrated in Figure 12. The device includes an outer sheath 88 into which is positioned a fluid flow control device ..."</p> <p>p.3, lines 4-6 "...a flow control device for the human body such as for ...pulmonic placement."</p> <p>p. 2, lines 13-16 "a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of ... a one-way flow restriction."</p>
wherein the obstructing member is a one-way valve to permit exhaled air to flow from the lung portion while precluding inhaled air from flowing into the lung portion.	<p>p.4, lines 2-3 "... a first fluid flow control device capable of one-way flow..."</p> <p>p. 5, line 5 "The valve body 24 acts in this embodiment as a one-way valve...."</p> <p>p.16, line 5 "One-way valve operation may be provided..."</p> <p>p.2, lines 13-16 "a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of ... a one-way flow restriction."</p>

APPLICATION OF TERMS OF CLAIM 18 TO APPLICATION

Claim 18 of the '569 application	Exemplary Disclosure of '569 application
A bronchial sub-branch obstruction device for reducing the size of a lung comprising	<p>p.3, lines 4-6 "...a flow control device for the human body such as for ...pulmonic placement."</p> <p>p.2, lines 13-16 "a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of ... a one-way flow restriction."</p>
an obstructing member dimensioned for insertion into a bronchial sub-branch communicating with a portion of the lung to be reduced in size,	<p>p.6, lines 6-8 "In the expanded state, the overall device is intended to fit with interference with the duct or passageway. Before expansion, easy insertion is contemplated with clearance."</p> <p>p.7, lines 7-9 "The frame is cylindrical with an OD in the insertion state of approximately .329[inches], a length of approximately .304[inches] and a thickness of approximately .005[inches] to .015[inches]."</p>
the obstructing member having an outer dimension which is so dimensioned as to make continuous contact with an inner dimension of the bronchial sub-branch to seal the bronchial sub-branch upon placement in the bronchial sub-branch to preclude air from being exhaled from the lung portion and inhaled into the lung portion for collapsing the portion of the lung and reducing the size of the lung,	<p>p.6, lines 6-7 "In the expanded state, the overall device is intended to fit with interference with the duct or passageway."</p> <p>p.7, lines 7-9 "The frame is cylindrical with an OD in the insertion state of approximately .329[inches], a length of approximately .304[inches] and a thickness of approximately .005[inches] to .015[inches]."</p> <p>p.4, lines 3-6 "The device includes a resilient seal 20 which, in this first embodiment, includes a cylindrical elastomeric or, more generally, polymeric material capable of sealing within the interior of a body duct or passageway."</p>

	<p>p. 4, lines 8-9 "[T]he seal has a substantially circular cross-section to fit within the body duct or passageway."</p> <p>p.7, lines 5-6 "...the outside diameter of the resilient seal 20 is approximately .349 [inches]"</p>
<p>wherein the obstructing member is a one-way valve to permit exhaled air to flow from the lung portion while precluding inhaled air from flowing into the lung portion.</p>	<p>p.4, lines 2-3 "... a first fluid flow control device capable of one-way flow..."</p> <p>p. 5, line 5 "The valve body 24 acts in this embodiment as a one-way valve...."</p> <p>p.16, line 5 "One-way valve operation may be provided..."</p> <p>p.2, lines 13-16 "a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of ... a one-way flow restriction."</p>

APPLICATION OF TERMS OF CLAIM 19 TO APPLICATION

Claim 19 of the '569 application	Exemplary Disclosure of '569 application
<p>A bronchial sub-branch obstruction system for reducing the size of a lung comprising:</p>	<p>p.3, lines 4-6 "...a flow control device for the human body such as for ...pulmonic placement."</p> <p>p.2, lines 13-16 "a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of ... a one-way flow restriction."</p>
<p>a conduit configured to be passed down a trachea, into a bronchus communicating with the trachea, and into a bronchial sub-branch communicating the bronchus with a lung portion to be reduced in size; and</p>	<p>p.3, lines 4-6 "...a flow control device for the human body such as for ...pulmonic placement."</p> <p>p. 11, lines 12-14 "Another mechanism for providing an elongate</p>

	expander and insertion tool is illustrated in Figure 12. The device includes an outer sheath 88 into which is positioned a fluid flow control device ..."
an obstructing member so dimensioned as to be guidable through the conduit and placed in the bronchial sub-branch to seal the bronchial sub-branch to preclude air from being exhaled from the lung portion and inhaled into the lung portion and to collapse the lung portion,	<p>p.11, lines 12-14 "Another mechanism for providing an elongate expander and insertion tool is illustrated in Figure 12. The device includes an outer sheath 88 into which is positioned a fluid flow control device ..."</p> <p>p.3, lines 4-6 "...a flow control device for the human body such as for ...pulmonic placement."</p> <p>p.2, lines 13-16 "a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of ... a one-way flow restriction."</p>
wherein the obstructing member is a one-way valve to permit exhaled air to flow from the lung portion while precluding inhaled air from flowing into the lung portion.	<p>p.4, lines 2-3 "... a first fluid flow control device capable of one-way flow..."</p> <p>p. 5, line 5 "The valve body 24 acts in this embodiment as a one-way valve...."</p> <p>p.16, line 5 "One-way valve operation may be provided..."</p> <p>p. 2, lines 13-16 "a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of ... a one-way flow restriction."</p>

APPLICATION OF TERMS OF CLAIM 20 TO APPLICATION

Claim 20 of the '569 application	Exemplary Disclosure of '569 application
A pulmonic fluid-flow control device, comprising:	<p>p. 2, line 13 "The present invention is directed to a body fluid flow control device..."</p> <p>p. 3, lines 4-6 "...a flow control device for the human body such as for ...pulmonic placement."</p> <p>p. 4, lines 2-3 "Figures 1 and 2 illustrate a first fluid flow control device capable of one-way flow, the sealing of a body passageway and pressure actuation."</p>
a one-way valve dimensioned for pulmonary placement,	<p>p. 2, line 13 "The present invention is directed to a body fluid flow control device..."</p> <p>p. 3, lines 4-6 "...a flow control device for the human body such as for ...pulmonic placement."</p> <p>p. 4, lines 2-3 "Figures 1 and 2 illustrate a first fluid flow control device capable of one-way flow, the sealing of a body passageway and pressure actuation."</p> <p>p. 5, line 5 "The valve body 24 acts in this embodiment as a one-way valve...."</p>
wherein the valve is configured to restrict fluid flow.	p. 2, lines 13-16 "The present invention is directed to a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of ... a one-way flow restriction."

APPLICATION OF TERMS OF CLAIM 21 TO APPLICATION

Claim 21 of the '569 application	Exemplary Disclosure of '569 application
The pulmonic fluid-flow control device of	

claim 20, wherein the valve has an outer diameter of 0.349 inches.	p.7, lines 5-6 "...the outside diameter of the resilient seal 20 is approximately .349 [inches]."
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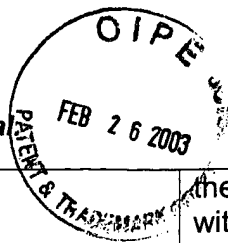
APPLICATION OF TERMS OF CLAIM 22 TO APPLICATION

Claim 22 of the '569 application	Exemplary Disclosure of '569 application
The pulmonic fluid-flow control device of claim 20, wherein the valve includes a valve body having a slit through which fluid can flow.	<p>p. 4, lines 14-18 "A valve body 24 is attached to the valve support 22 about the outer periphery of the body. ... The body 24 is shown in this first embodiment to define a passage which is shown to be a single slit."</p> <p>p. 9, lines 11-12 "A variety of slits or other mechanisms may be employed to achieve a flow through a passage"</p> <p>Figure 1, slit 26, and Figure 9, passage 58 in the form of a slit.</p>

APPLICATION OF TERMS OF CLAIM 23 TO APPLICATION

Claim 23 of the '569 application	Exemplary Disclosure of '569 application
A pulmonic fluid-flow control system, comprising:	<p>p. 2, line 13 "The present invention is directed to a body fluid flow control device..."</p> <p>p. 3, lines 4-6 "...a flow control device for the human body such as for ...pulmonic placement."</p> <p>p. 4, lines 2-3 "Figures 1 and 2 illustrate a first fluid flow control device capable of one-way flow, the sealing of a body passageway and pressure actuation."</p>
an elongate passage or outer sheath for positioning a valve; and	p. 11, lines 4-7 "An elongate expander is illustrated in Figure 11. A balloon 84 is presented at the end of an elongate passage 86 through which pressure may be transmitted.

	<p>The fluid flow control device can be inserted on the mechanism making up the passage 86 and balloon 84."</p> <p>p. 11, lines 12-14 "Another mechanism for providing an elongate expander and insertion tool is illustrated in Figure 12. The device includes an outer sheath 88 into which is positioned a fluid flow control device ..."</p>
<p>a one-way valve so dimensioned as to be guidable on the elongate passage or into the outer sheath,</p>	<p>p. 4, lines 2-3 "Figures 1 and 2 illustrate a first fluid flow control device capable of one-way flow..."</p> <p>p. 5, line 5 "The valve body 24 acts in this embodiment as a one-way valve..."</p> <p>p. 11, lines 6-7 "The fluid flow control device can be inserted on the mechanism making up the passage 86 and balloon 84."</p> <p>p. 11, lines 12-14 "Another mechanism for providing an elongate expander and insertion tool is illustrated in Figure 12. The device includes an outer sheath 88 into which is positioned a fluid flow control device ..."</p>
<p>the valve so dimensioned for pulmonary placement,</p>	<p>p. 3, lines 4-6 "...a flow control device for the human body such as for ...pulmonic placement."</p> <p>p. 4, lines 4-9 "The device includes a resilient seal 20 which, in this first embodiment, includes a cylindrical elastomeric or, more generally, polymeric material capable of sealing within the interior of a body duct or passageway. ... [T]he seal has a substantially circular cross section to fit within the body duct or passageway."</p> <p>p.6, lines 6-8 "In the expanded state,</p>



	the overall device is intended to fit with interference with the duct or passageway. Before expansion, easy insertion is contemplated with clearance."
wherein the valve is configured to restrict fluid flow.	p. 2, lines 13-16 "The present invention is directed to a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of ... a one-way flow restriction."

APPLICATION OF TERMS OF CLAIM 24 TO APPLICATION

Claim 24 of the '569 application	Exemplary Disclosure of '569 application
The pulmonic fluid-flow control device of claim 23,	
wherein the valve has an outer diameter of 0.349 inches.	p.7, lines 5-6 "...the outside diameter of the resilient seal 20 is approximately .349 [inches]."

APPLICATION OF TERMS OF CLAIM 25 TO APPLICATION

Claim 25 of the '569 application	Exemplary Disclosure of '569 application
The pulmonic fluid-flow control device of claim 23,	
wherein the valve includes a valve body having a slit through which fluid can flow.	<p>p. 4, lines 14-18 "A valve body 24 is attached to the valve support 22 about the outer periphery of the body. ... The body 24 is shown in this first embodiment to define a passage which is shown to be a single slit."</p> <p>p. 9, lines 11-12 "A variety of slits or other mechanisms may be employed to achieve a flow through a passage"</p> <p>Figure 1, slit 26, and Figure 9, passage 58 in the form of a slit.</p>